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8 UNITED STATES DISTRICT COURT
9 SOUTHERN DISTRICT OF CALIFORNIA
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11 REMBRANDT DIAGNOSTICS, LP.,
12 Plaintiff,
13 v.
14 INNOVACON, INC., ,
15 Defendant.
16

Case No.: 3:16-cv-0698-CAB-(NLS)

CLAIM CONSTRUCTION ORDER

17 This litigation involves a breach of contract claim brought by Plaintiff Rembrandt
18 Diagnostics, L.P. (“Rembrandt”) against Defendant Innovacon, Inc., for royalties alleged
19 due on the sale of urine test cups. A 2004 Patent License Agreement between Rembrandt’s
20 predecessor-in-interest, Assurance Biotech, LLC, and Innovacon’s predecessor-in-interest,
21 Applied Biotech, Inc., grants Applied Biotech, and its affiliates rights to certain patents,
22 including U.S. Patent No. 6,548,019; and its foreign counterparts: Canadian Patent No.
23 2,324,413; EP Patent No. 1,028,806; and Taiwanese Patent No. 461827. [Doc. No. 41, Ex.
24 3.¹] According to the terms of the 2004 Agreement, Applied Biotech, and its affiliates,
25 have an exclusive, worldwide right to make and sell urine test cups for use in the drugs of
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28 ¹ Document numbers and page references are to those assigned by CM/ECF for the docket entry.

1 abuse market that are covered by the claims of the ‘019 patent and its foreign counterparts,
2 in exchange for royalty payments.

3 Rembrandt alleges that products sold by Innovacon in the United States, Canada, the
4 United Kingdom and Tawian are “urine test cup for use in the drugs of abuse market” that
5 “would infringe claim[s] of ...[the] Licensed Patents absent [the 2004] Agreement.” [*Id.*
6 at ¶1.5.] It is further alleged that no royalty payments have been made as required by the
7 2004 Agreement. Innovacon contends that it has made no sales of products that infringe
8 any claim of the ‘019 Patent or its foreign counterparts. To assist in the determination of
9 whether royalty payments are owed pursuant to the Agreement, the parties requested the
10 Court construe certain claims of the patents at issue.

11 The parties submitted their proposed claim construction briefs in accordance with
12 the Court’s scheduling order [Doc. Nos. 144, 145, 156, 157].² On November 13, 2017, the
13 Court held a Claim Construction hearing in this matter. [Doc. Nos. 160, 161.] For the
14 reasons stated on the record and set forth below, the Court construes the submitted claim
15 terms as follows.³

16 **A. The ‘019 Patent⁴**

17 The ‘019 Patent has one independent claim. [*Id.* at 8-9, Col. 8:41- Col. 9:2.] The
18 parties requested the Court construe the terms set forth in bold. The invention claimed in
19 Claim 1 is:

23
24 ² Innovacon’s Motion [Doc. No. 159] to Strike the Declaration of Jin Po Lee [Doc. No. 158] as untimely
is **GRANTED**.

25 ³ Prior to the hearing the parties agreed to the construction of “ambient pressure” as *the pressure of the*
26 *surrounding medium, such as a gas or a liquid*, and “an ambient pressure within the flow control
27 *channel equivalent to the ambient pressure outside of the flow control channel*” as *the pressure of the*
28 *medium within the flow control channel is equivalent to the pressure of the medium outside the flow*
control channel. [Doc. No. 144 at 5-6; Doc. No. 133-1 at 9 and 11.] The Court hereby adopts those
stipulated constructions.

⁴ Doc. No. 144-4 at 2-10.

1 1. **A device for collecting and assaying a sample of biological fluid**, the device
2 comprising:

3 (a) a flow control channel defined by at least one liquid pervious side joined to liquid
4 impervious sides, wherein the internal dimensions of the flow control channel are
5 sufficient to permit placement therein of an assay test strip;

6 (b) an assay test strip within the flow control channel, wherein the assay test strip
7 has a **sample loading zone** therein, and wherein further **the assay test strip is**
8 **disposed within the flow control channel** so that sample fluid contacts the sample
9 loading zone at a liquid pervious side of the flow control channel; and,

10 (c) a sample fluid container having a base, an open mouth, and walls connecting the
11 base to the mouth;

12 **wherein the flow control channel is disposed inside the sample fluid container**
13 **with the liquid pervious side oriented [toward] the base of the sample fluid**
14 **container so that the assay sample fluid, when added to the container, is**
15 **delivered to the sample loading zone of the assay test strip by entry through a**
16 **liquid pervious side of the flow control channel** without migration through an
17 **intermediate structure**, and wherein entry of fluid into the flow control channel
18 creates an ambient pressure within the flow control channel equivalent to the
19 ambient pressure outside of the flow control channel, thereby eliminating a pressure
20 gradient along which excess sample fluid could flow into the flow control channel.

21 The parties also requested the Court construe the following term of Claim 2.

22 2. A device according to claim 1, wherein the sides of the flow control channel are
23 **loosely fitted** around the assay test strip.

24 a. **A device for collecting and assaying a sample of biological fluid**

25 Rembrandt contends that the preamble of the claim, **a device for collecting and**
26 **assaying a sample of biological fluid**, is limiting as it is “necessary to give life, meaning
27 and vitality” to the claim. *Catalina Mktg Inter. v. Coolsavings.com*, 289 F.3d 801, 808
28 (Fed. Cir. 2002). Specifically, Rembrandt argues that the preamble limits the claimed
29 **device** to a “single unitary structure for conducting a test.” [Doc. No. 144 at 17.] This is
30 supported, according to Rembrandt, by the specification’s reference to “a combination
31 assaying device and collection chamber which is capable of easily collecting and testing a
32 biological fluid sample, such as urine, while maintaining the sample unadulterated and
33 secure,” and the Figures of the patent which depict unitary arrangement. [*Id.* at 15.]

1 Innovacon contends that the preamble of the claim is not limiting, rather the
2 preamble states a purpose or intended use for the set of limitations in the body of the claim
3 that completely sets forth the invention. *See Catalina Mktg*, 289 F.3d at 808 (where a
4 patentee defines a structurally complete invention in the claim body and uses the preamble
5 only to state a purpose or intended use, the preamble is not limiting.) **Device** in this claim
6 phrase, according to Innovacon, is not a limitation but merely a descriptive name for the
7 set of limitations in the body of the claim. *See IMS Tech., Inc. v. Haas Automation, Inc.*,
8 206 F.3d 1422, 1434 (Fed. Cir. 2000) (“The phrase ‘control apparatus’ in the preamble
9 merely gives a descriptive name to the set of limitations in the body of the claim that
10 completely set forth the invention.”)

11 The Court agrees with Innovacon, that the preamble is not limiting. The preamble
12 recites the intended purpose of the invention and the body of the claim defines a structurally
13 complete invention. Although the specification discloses as an embodiment of the
14 invention a combination assay test strip/assay sample fluid collection cup, the specification
15 also recognizes that “those of ordinary skill in the art will appreciate that flow control
16 means of the invention common to each embodiment may be utilized in any test-strip based
17 immunoassay format in which restricting the flow of fluid through the test strip is desired.”
18 [Doc. No. 144-4 at 7, Col. 5:15-20.] The claim is not limited to a single unitary structure
19 for conducting a test, as Rembrandt proposes. The claim would be infringed by any device
20 encompassing all the limitations in the body of the claim. *IMS Tech.*, 206 F.3d at 1434.
21 The Court finds **a device for collecting and assaying a sample of biological fluid** to be a
22 descriptive name for the set of limitations and an intended use. No construction of the
23 preamble is required.

24 b. **sample loading zone**

25 **Sample loading zone** is explicitly defined in the patent to be *an area of a* [sic] *assay*
26 *test strip on which a fluid analyte sample is applied for migration to the test zone.* [Doc.
27 No. 144-4 at 5, Col. 2:35-39, 50-52.] The Court finds no reason to deviate from the express
28 definition provided in the patent.

1 c. **the assay test strip is disposed within the flow control channel**

2 The parties agree the limitation requires that the assay test strip be contained in the
3 flow control channel. The disagreement was whether “disposed within” should be
4 construed to require the strip be contained entirely in the channel or if it can protrude at the
5 pervious end such that the sample loading zone of the strip extends beyond the channel in
6 the manner described in the specification and depicted in Figure 3. [*Id.* at 3 and 7, Col.
7 6:14-16, 38-40; Figs. 3 and 4.] The plain language of the entire claim and the prosecution
8 history inform this construction issue.

9 Originally filed as Claim 3, the claim recited “an assay test strip disposed within the
10 flow control channel, wherein the assay test strip has a sample loading zone therein, and
11 wherein further the assay test strip is disposed within the flow control channel so that
12 sample loading zone *is flush with, or protrudes from,* a liquid pervious side of the flow
13 control channel.” [Doc. No. 147-4 at 39, emphasis added.] The claim further recited that
14 “assay sample fluid is introduced into the assay test strip solely by wicking therethrough
15 on contact of the sample loading zone with assay sample fluid.” [*Id.* at 40.]

16 In response to an Office Action rejecting the claims, the patentee amended, and the
17 apparatus claim, now Claim 1, remained relatively unchanged as “an assay test strip within
18 the flow control channel, wherein the assay test strip has a sample loading zone therein,
19 and wherein further the assay test strip is disposed within the flow control channel so that
20 sample loading zone *is flush with, or protrudes from,* a liquid pervious side of the flow
21 control channel.” [Doc. No. 147-5 at 45, emphasis added.]

22 To distinguish the invention over prior art, the patentee highlighted that in the
23 invention sample fluid is delivered to the sample loading zone through the liquid pervious
24 side of the control channel. The pressure in the channel limits the rate “at which sample
25 will flow into the channel to contact the sample loading zone.” [*Id.* at 58, 63.] The claim
26 was amended to add that the assay sample fluid when added to the container “is delivered
27 directly to the sample loading zone through a liquid pervious side of the flow control
28 channel,” and the “assay sample fluid is introduced into the flow control channel and onto

1 the assay test strip solely by wicking on contact of the sample loading zone with assay
2 sample fluid.” [*Id.* at 65.]

3 The claims were again rejected. [Doc. No. 147-6 at 15-19.] In response, the patentee
4 initially offered no further amendments but challenged the examiner’s interpretation and
5 application of the prior art. [*Id.* at 27-38.] The examiner was not persuaded and
6 specifically found that prior art disclosed direct contact of a fluid sample to the sample
7 loading zone without migration through an intermediate structure. The claims therefore
8 stood rejected. [*Id.* at 41.]

9 Following an interview, the patentee submitted an amended Claim 1 to “define
10 Applicants’ invention with greater particularity.” [*Id.* at 51.] Claim 1 was amended to
11 recite an “assay test strip within the flow control channel, wherein the assay test strip has
12 a sample loading zone therein, and wherein further the assay test strip is disposed within
13 the flow control channel so the *sample fluid contacts the* sample loading zone [~~is flush~~
14 ~~with, or protrudes from~~] *at* a liquid pervious side of the flow control channel.” [*Id.* at 55.]
15 The “flush with or protrudes from” language was removed.

16 The claim was further amended in a supplementary filing to clarify “that the assay
17 sample fluid, when added to the container, is delivered [~~directly~~] to the sample loading
18 zone of the assay test strip *by entry* through a liquid pervious side of the flow control
19 channel.” [*Id.* at 69.] Direct delivery to the sample loading zone was replaced with
20 delivery by entry through the liquid pervious side of the flow control channel.

21 The claim was allowed, in part, because the prior art did not teach or suggest a device
22 in which “the sample fluid is delivered to the sample loading zone of the test strip by entry
23 though [sic] a liquid pervious side of the flow control channel.” [Doc. No. 147-7 at 2.]

24 Rembrandt does not address the plain language of the claim as finally allowed, that
25 requires the sample fluid be delivered to the sample loading zone, not directly, but by entry
26 through the flow control channel. Rembrandt relies on the written description and the
27 illustrated preferred embodiment to construe **disposed within** as encompassing an assay
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1 test strip with its sample loading zone protruding from the flow control channel in direct
2 contact with the fluid sample.

3 A claim interpretation that excludes a preferred embodiment from the scope of the
4 claim is rarely, if ever, correct. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F3d. 1576, 1583
5 (Fed. Cir. 1996). However, the language of the claim as amended no longer supports a
6 protruding sample loading zone that directly contacts the fluid outside the channel. The
7 plain language of the claim is for a device in which the flow control channel is disposed
8 inside the container with the liquid pervious side oriented toward the base⁵ and when liquid
9 is added it is delivered to the sample loading zone by entry through the liquid pervious side
10 of the flow control channel. These amendments were made after numerous rejections
11 based on prior art that the examiner argued disclosed sample fluid directly contacting the
12 sample loading zone. Although the patentee disagreed with the examiner's understanding
13 of the scope and operation of the prior art, he ultimately amended the claim to remove
14 direct contact between the fluid and the loading zone and claim the contact occurs by entry
15 of the fluid through the flow control channel.

16 In this case the unambiguous language of an amended claim and the prosecution
17 history result in the exclusion of a preferred embodiment that teaches the loading zone can
18 protrude from the channel. *See Elekta Instrument S.A., v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d
19 1302, 1308 (Fed Cir. 2000) (amendment disclaiming preferred embodiment compelled
20 adopting construction excluding that embodiment). Based on the plain language of the
21 claim and the prosecution history, the Court therefore construes **the assay test strip is**
22 **disposed within the flow control channel** as *the assay test strip is disposed entirely within*
23 *the flow control channel*.

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27 ⁵ The plain language of the amended claim also precludes a preferred embodiment in which the liquid
28 pervious side and the sample loading zone are oriented toward the mouth of the container. [Doc. No.
144-4 at 4 and 8, Col. 7:29-40, Fig. 7.]

1 d. **intermediate structure**

2 An **intermediate structure** is construed as *a wicking material or other transferring*
3 *means between the fluid and assay test strip*. The patent explicitly defines the sample
4 loading zone as part of the assay test strip. [Doc. No. 144-4 at 5, Col. 2:50-56.] Therefore
5 the construction is further clarified that the sample loading zone of an assay test strip does
6 not meet the definition of an intermediate structure. [See Hearing Transcript, Doc. No. 161
7 at 34-36.]

8 e. **wherein the flow control channel is disposed inside the sample fluid**
9 **container with the liquid pervious side oriented [toward] the base**
10 **of the sample fluid container so that the assay sample fluid, when**
11 **added to the container, is delivered to the sample loading zone of**
12 **the assay test strip by entry through a liquid pervious side of the**
13 **flow control channel**

14 Rembrandt argues that this wherein clause requires that the assembled device, i.e.,
15 the flow control channel with the inserted assay test strips, must be placed in the container
16 prior to the fluid being added. Innovacon argues that this is not a method claim and the
17 language only requires that the structural elements function in accordance with the
18 limitations whether the flow control channel is introduced to the container before or after
19 the fluid is introduced.

20 This is an apparatus claim not a method claim. “Apparatus claims cover what a
21 device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d
22 1464, 1468 (Fed. Cir. 1990). The claimed device has certain structural limitations that
23 perform a particular function when exposed to fluid. The specification provides that the
24 flow control channel can be positioned in the container prior to the fluid sample being
25 added, or alternatively it can be immersed into the fluid already in the container. [Doc. No.
26 144-4 at 7, Col. 6:40-45 and Col. 5:62-64.] If one makes and sells the device, presumably
27 without fluid, the device could be found to infringe if it has all the structural limitations to
28 function as disclosed.

1 The Court finds **when added to the container** is a functional limitation describing
2 how the device must function when it comes into contact with liquid, not a temporal
3 requirement as to when the liquid is introduced to the container.

4 f. **loosely fitted**

5 The Court determined that **loosely fitted** in the context of the patent did not require
6 construction and has no special or unusual meaning to be understood by a trier of fact. [*Id.*
7 at 36-42.] Claim 1 requires that the flow control channel have “internal dimensions ...
8 sufficient to permit placement therein of an assay test strip.” [Doc. No. 144-4 at 8, Col.
9 8:44-48.] Dependent Claim 2 requires that “the sides of the flow control channel are **loosely**
10 **fitted** around the assay test strip.” [*Id.* at 9, Col. 9:3-5.] The Court finds a trier of fact can
11 understand and make that determination without further construction.

12 **B. The ‘413 Patent**⁶

13 The ‘413 patent is the Canadian counterpart of the ‘019 patent. Claim 1 claims:

14 1. A device for collecting and assaying a sample of biological fluid comprising:

15 (a) **contiguous** flow control channels for each of a multiplicity of assay strips, each
16 channel being defined by at least one liquid pervious side joined to liquid
17 impervious, wherein the internal dimensions of the flow control channel are
18 sufficient to permit placement therein of an assay test strip;

19 (b) assay test strips disposed within the flow control channels, wherein the assay test
20 strips have a sample loading zone therein, and wherein further each assay test strip
21 is disposed within the flow control channel so the sample loading zone protrudes
22 from the liquid pervious side of the flow control channels; and,

23 (c) a liquid sample container having a base, an open mouth closable with a cap and
24 walls connecting the base to the mouth, said liquid container being large enough to
25 contain said liquid control channels and protruding assay strips, wherein the volume
26 capacity of the assay sample liquid collection container is such that the total liquid
27 pressure obtainable within the container is maintained at or below 1 atmosphere,
28 wherein further each flow control channel is placed into the assay sample liquid
collection container such that a liquid pervious side of each flow control channel
will be placed in contact with the assay sample liquid when added to the container
or when the container is inverted;

⁶ Doc. No. 144-4 at 12-34.

1 (d) wherein the ambient pressure within each flow control channel is equivalent to
2 the ambient pressure outside the flow control channel; and
3 (e) wherein further the assay sample liquid is introduced into each assay test strip
4 solely by wicking there through on contact of the sample loading zone with the assay
sample liquid.

5 The parties requested construction of **contiguous**, which the Court construed as *next*
6 *to or together in sequence*. [Doc. No. 161 at 42-45.]

7 It is **SO ORDERED**.

8 Dated: December 7, 2017



Hon. Cathy Ann Bencivengo
United States District Judge